DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 14, 2015

Koven Technology, Inc.
Ms. Heather Bell, President
12125 Woodcrest Executive Dr., Ste. 320
St. Louis, MO 63141

Re: K143332
Trade/Device Name: FAST Sphyg by Koven
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: February 25, 2015
Received: March 3, 2015

Dear Ms. Bell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number: **K143332**

Device Name: **FAST Sphyg by Koven**

Indications for Use:

The device is a sphygmomanometer intended to be used with a stethoscope or Doppler for indirect measurement of arterial blood pressure. This device includes an aneroid gauge. Koven Technology, Inc. intends to provide the device for use by healthcare providers. Our product is for both hospital and clinical use and are intended for pediatric through adults, excluding neonates.

Type of Use *(Select one or both, as applicable)*

Prescription Use (Part 21 CFR 801 Subpart D)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary, Section 5

Date of Preparation: October 27, 2014

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with 21 CFR Sec. 807.92. A 510(k) Statement is not provided.

Company making this submission:

Submitter / Owner	
Company Name:	**Koven Technology, Inc.**
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Responsible Person:	**Ms. Heather Bell, President**
E-Mail Address:	**koven@koven.com**

Application Consultant	
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Fax:	314.542.6020
E-mail Address:	koven@koven.com

Device Name:

Trade/Proprietary Name:	**FAST Sphyg by Koven**
Common/Usual Name:	**Blood Pressure Cuff**
Regulation Number:	**870.1120**
Product Code:	**DXQ**

Substantial Equivalency:

The FAST Sphyg by Koven is substantially equivalent to other devices intended for use with a stethoscope or Doppler for indirect measurement of arterial blood pressure. The predicate device is the Aneroid and Mercurial Sphygmomanometer manufactured by American Diagnostic Corp., West Babylon, NY, with S.E number of K962655.

Parameter	FAST Sphyg by Koven (This submission.)	Aneroid Sphygmomanometers K962655
Indication for Use Statement	The device is a sphygmomanometer intended to be used with a stethoscope or Doppler for indirect measurement of arterial blood pressure. This device includes an aneroid gauge. Koven Technology, Inc. intends to provide the device for use by healthcare providers. Our product is for both hospital and clinical use and are intended for pediatric through adults.	The device is a sphygmomanometer intended to be used with a stethoscope for indirect measurement of arterial blood pressure. This device will include an aneroid gauge, as well as, a mercurial manometer for some models. American Diagnostic intends to provide the device for use by healthcare providers. Our products are for both hospital and home use and are intended for newborns through adults. Our device (sphygmomanometer) will be sold over the counter.
Regulation #	21 CFR § 870.1120	21 CFR § 870.1120
Product Codes	DXQ	DXQ
Target Patient	Humans	Humans
Gauge	Aneroid Gauge	Aneroid Gauge
Cuff inflation	User controlled inflation button	User controlled hand pumped
Cuff deflation	User controlled, trigger type	User controlled, trigger type

General Overview:

The FAST Sphyg by Koven is an aneroid sphygmomanometer that uses the auscultatory blood pressure technique in combination with a stethoscope or Doppler and occluding cuff to determine systolic and diastolic blood pressure measurement.

The FAST Sphyg includes an aneroid gauge, as well as a battery powered air pump so the user can control the inflation. When the activation button is pushed on the device, the air pump inflates the cuff. When the activation button is released, inflation stops, but the system remains pressurized. The aneroid gauge on the device reflects this increase in pressure, which is displayed in mmHg. A release valve is activated through a trigger switch to manually deflate the cuff and notate the blood pressure measurement.

Clinical Applications:

Non-invasive arterial blood pressure measurement.

Principles:

Auscultatory blood pressure measurement:

As the heart beats, blood forced through the arteries cause a rise in pressure, called systolic pressure, followed by a decrease in pressure as the heart's ventricles prepare for another beat. This low pressure is called the diastolic pressure.

The sphygmomanometer inflates a cuff above expected systolic pressure using a pump. As the air release valve is opened, cuff pressure (slowly) decreases. When the cuff's pressure equals the arterial systolic pressure, blood begins to flow past the cuff, creating blood flow turbulence and audible sounds (called Korotkoff sounds). Using a stethoscope, these sounds are heard and the cuff's pressure is recorded. The blood flow sounds will continue until the cuff's pressure falls below the arterial diastolic pressure. The pressure when the blood flow sounds stop indicates the diastolic pressure.

Performance Standards:

No performance standards have been established for the FAST Sphyg under section 514 (864.5700) of the Federal Food and Drug Act. However, the FAST Sphyg has been designed and tested to meet the following standards:

- ISO 81060-1:2007 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type

- IEC 60601-1 Medical electrical equipment 2007:
  Protection class against electric shock:
  Class II device
  Internally powered equipment
  Protection grade against electric shock:
  Type B applied part

- IEC 60601-1-2 Medical electrical equipment – Part 1-2: Collateral Standard Electromagnetic compatibility (2007):
  Guidance and manufacturer's declaration - electromagnetic emissions and immunity

Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The FAST Sphyg uses RF energy only for its internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The FAST Sphyg is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Flicker Emissions IEC 61000-3-3	Not Applicable	

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst	±2kV for power supply lines ± 1kV for	±2kV for power supply lines	Mains power should be that of a typical commercial or hospital environment.

IEC 61000-4-4	input/output lines	± 1kV for input/output lines	
Surge IEC 61000-4-5	±1kV differential mode ± 2kV common mode	±1kV differential mode ± 2kV common mode	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	< 5% UT (> 95% dip in UT) for 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 s	< 5% UT (> 95% dip in UT) for 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 s	Mains power should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the FAST Sphyg, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FAST Sphyg is used exceeds the applicable RF compliance level above, the FAST Sphyg should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the FAST Sphyg. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Indication for Use Statement:

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Contraindications:

Safety and effectiveness with neonate cuff sizes 1 through 5 is not established.

Material that touches skin:

There are no materials on the FAST Sphyg that make contact with the patient skin. Cuffs sold separately.